

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

GILDA HAGAN-BROWN,)
)
 Plaintiff,)
)
 vs.) 1:14-CV-01614-AJT-JFA
)
 ELI LILLY AND COMPANY,) Hon. Anthony J.
)
 an Indiana corporation,) Trenga
)
 Defendant.)

The videotaped deposition of MATT KUNTZ, taken in the above-entitled cause, before Paula Ann Erickson, Certified Shorthand Reporter, Registered Professional Reporter and Notary Public, on May 6, 2015, at the Double Tree Hotel, 510 East Illinois Route 83, Mundelein, Illinois, at the approximate hour of 1:36 p.m.

Reported by: Paula A. Erickson, CSR, RPR, CLR

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1 Effected Regulation?

2 A. Yes.

3 Q. And what is that?

4 A. It's a type of supplement, so it's
5 changes being affected are -- is a mechanism by
6 which the sponsor or the applicant can modify
7 labeling without prior approval -- I'm sorry.
8 You can update and implement a change to your
9 labeling prior to receiving FDA's approval.

10 Q. And are you familiar with the
11 circumstances in which that is permitted?

12 A. Yes, I am.

13 Q. What are those circumstances?

14 A. They include different types of
15 manufacturing changes and also can include
16 safety updates to labeling.

17 Q. Specifically are they permitted --
18 Strike that.

19 You said that there is other types of
20 applications, however, that require prior
21 approval; is that right?

22 A. Right.

23 Q. Are those frequently called -- What are
24 those called within the regulatory jargon?

25 A. Prior Approval Supplement, PAS.

1 Q. Okay. And the Changes Being Effected
2 Regulations are just those called CBEs?

3 A. CBEs.

4 Q. And Prior Approval Supplements, what do
5 those relate to?

6 A. Those would relate to substantial
7 modifications to labeling that aren't
8 necessarily immediately a safety-related issue
9 but sometimes they have some sort of safety
10 component but often they can also be like new
11 clinical data to support a dosing instructions
12 or supplements for new populations to be added
13 to labeling.

14 Q. And for Prior Approval Supplements, any
15 proposed changes have to first be approved by
16 the FDA before they are implemented?

17 A. That's correct.

18 Q. Whereas, in a CBE change, they can be
19 implemented immediately; is that true?

20 A. Yes.

21 Q. They also are, of course, subject to
22 FDA review, though, correct?

23 A. Yeah. They are still subject to FDA
24 review and ultimately FDA approval.

25 Q. Okay. During the time that you worked

1 as a US Regulatory Associate for Cymbalta, did
2 you ever have an occasion to see Lilly submit a
3 CBE?

4 A. I don't recall to be honest. I just --
5 I don't know.

6 Q. Well, during your time as a US
7 Regulatory Associate for Cymbalta, do you recall
8 Lilly submitting any Prior Approval Supplements?

9 A. Yes. I remember -- and, you know,
10 honestly, I wouldn't be surprised there would be
11 CBEs. Those are just common lifecycle
12 management activities. You know, as you have
13 more data available, you would naturally want to
14 the include it in your NDA.

15 Q. That was actually going to be my next
16 question. Are CBEs and Prior Supplemental
17 Applications -- Prior Approval Supplements, are
18 they common as part of the regulatory
19 interfacing between Lilly and the FDA?

20 MR. TEEL: Object to the form. You can
21 answer.

22 THE WITNESS: Yeah. I mean, they would
23 be normal course of business and I would have
24 expected both types of supplements to be
25 submitted.

1 BY MR. WISNER:

2 Q. Okay. I just want to -- We are going
3 to come back to Lilly in a second. I just want
4 to know a little bit more about you. Do you
5 have any medical training?

6 A. Yes. My background is in pharmacy.

7 Q. Can you please explain to the jury what
8 your educational background is?

9 A. Yeah. Sure. So I have a bachelor's
10 degree in pharmacy and then I also have what's
11 called a Pharm.D. in pharmacy which is --
12 required a couple more years of pharmacy and
13 then I have also an MBA.

14 Q. And you say you have a bachelor's in
15 pharmacy. Can you explain to the jury what that
16 means? What is the area of study of pharmacy?

17 A. So just pharmacy practice in general is
18 what your degree is in. I didn't specialize or
19 get any further certifications, so the
20 bachelor's degree in pharmacy is a five-year
21 program that is a general pharmacy curriculum.

22 Q. Is the purpose once you have completed
23 the degree, you can open up a pharmacy? Is that
24 the idea?

25 A. Sure. You could open a pharmacy, you

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1 Q. That's okay.

2 A. I don't really remember anything else
3 about it other than that. I think we were -- we
4 were requested to go back and look for any
5 submissions to FDA or any sort of correspondence
6 with FDA around Discontinuation Adverse Events.

7 Q. So it had to have been before
8 August 2012; is that fair?

9 A. Yes. It was.

10 Q. Okay. Do you recall if it was a class
11 action or a personal injury case?

12 A. I'm sorry, I don't.

13 Q. Do you even know what those differences
14 are?

15 A. I do. Sort of in the broadest sense at
16 least.

17 Q. Okay. Okay. Do you recall working
18 on -- And just do you mind if I use the word
19 withdrawal or do you have a preference one way
20 or the other?

21 A. I mean, I use the term Discontinuation
22 Adverse Events, but I don't have a preference
23 what you use.

24 Q. I might use withdrawal. I might use
25 discontinuation symptoms. I will try to use

1 discontinuation symptoms but I might mess up so
2 I apologize if I do.

3 A. That's fine. Okay.

4 Q. When -- Do you recall doing any
5 regulatory activities related to discontinuation
6 symptoms?

7 A. With FDA, no, I don't.

8 Q. Do you recall doing any
9 discontinuation-related issues with any
10 regulatory body?

11 A. I don't recall.

12 Q. Now, you said you were a US Regulatory
13 Associate. Did you also work on regulatory
14 issues in other countries?

15 A. Not directly, although, we would be
16 aware of any sort of ongoing interactions with
17 at least the major regulatory authorities
18 outside the US and, again, in the interest of
19 patient safety, Lilly would often try to
20 harmonize labeling, to the extent it was
21 possible, given the different regional
22 preferences and jurisdictions.

23 Q. The -- You have mentioned the word
24 harmonize a couple of times. Can you explain to
25 the jury what that means?

1 A. Yeah. So the -- Regulatory authorities
2 in each country have their own set of
3 requirements, regulations, and often
4 pharmaceutical companies are trying to develop
5 products to be marketed in worldwide, right, and
6 so it becomes difficult when you have to develop
7 a product under a certain set of rules in the US
8 and a different set of rules in Europe and a
9 different set of rules even for Japan and so
10 harmonization is about trying for these three
11 major regulatory regions to attempt to at least
12 standardize, to the extent possible, their
13 requirements.

14 Q. You said these three major ones. Are
15 those the three primary regulatory groupings
16 of -- of -- are those the three primary
17 regulatory groupings?

18 A. Yes.

19 Q. And, I mean, there is obviously more
20 than three countries in the world.

21 A. Right.

22 Q. What is your understanding of why there
23 is those three primary regulatory groupings?

24 A. Well, those are the -- this is my
25 understanding -- is that these are the three

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1 meaningful.

2 BY MR. WISNER:

3 Q. You said fair and balanced. That's
4 actually a term of art within Lilly, right?

5 A. A term of art? I believe, yes.

6 Q. It's actually a goal set by Lilly in
7 its product labeling?

8 A. I think it's a goal established. I'm
9 not sure if it's in regulation or not but yeah.
10 It's a common vernacular in regulatory.

11 Q. And can you explain to the jury what
12 fair and balanced means?

13 A. Well, it would just mean that the data
14 are conveyed in a manner that is accurate, not
15 misleading, not overstating or minimizing the
16 data. You know, it's just it's a fair and
17 balanced representation of the data.

18 Q. During your time at Eli Lilly, did you
19 ever have an occasion where you thought that
20 Lilly was not being forthright or honest in its
21 disclosures in its US product labeling.

22 A. No.

23 Q. Previously I mentioned the word
24 withdrawal and discontinuation symptoms. What
25 is your understanding of that?

1 MR. TEEL: Object to the form.

2 MR. WISNER: Let me ask that a
3 different way. Strike that.

4 BY MR. WISNER:

5 Q. What is -- What is discontinuation
6 symptoms, to the best of your knowledge?

7 A. For Cymbalta specifically?

8 Q. Precisely. Yes.

9 A. That if you abruptly -- well, I don't
10 even know if it's always abruptly; but if you
11 stopped Cymbalta, you may experience certain
12 adverse events around the time you discontinue
13 and I believe things like nausea, jitteriness
14 but I don't remember all the others. There is a
15 list of them I know.

16 Q. Sure. And what is your understanding
17 of how frequently that withdrawal risk occurs?

18 A. How frequently?

19 Q. Uh-huh.

20 A. Well, I do know that in the preparation
21 for today, I was made aware that in the European
22 label, it I think cites something like
23 45 percent or something of that nature.

24 Q. But prior to your preparation, you
25 weren't aware of that fact?

1 A. I didn't recall it, no.

2 Q. Okay. While you were a US Regulatory
3 Associate, was the issue -- the safety issue of
4 discontinuation symptoms something that you
5 considered to be important?

6 A. I don't remember ever having any sort
7 of concern or issue with the way that the
8 discontinuation events were labeled in the US.

9 Q. And during your time -- And did you
10 ever hear any discussions amongst anybody at Eli
11 Lilly that the labeling was somehow deficient
12 or -- Strike that.

13 During your time at Eli Lilly, did you
14 ever hear anyone discussing or mention to you
15 that the Cymbalta label with regards to
16 discontinuation symptoms was deficient?

17 A. I don't recall ever hearing that.

18 Q. Do you ever recall having any specific
19 conversation with anybody within Eli Lilly, and
20 I say this with the exclusion of any
21 conversations you may have had with an attorney,
22 but do you recall ever having any conversations
23 with anybody in Eli Lilly about the
24 discontinuation warning in the Cymbalta label
25 for the US?

1 A. The only conversation I ever remember
2 was when we received notification of that --
3 that lawsuit.

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4 Q. Okay. And following hearing about that
5 lawsuit, did you discuss the lawsuit with any
6 non-attorney individuals within Eli Lilly?

7 A. I'm not sure. I mean, I remember we --
8 there was a group of people that met and what I
9 recall of that meeting was that we were made
10 aware of this lawsuit and that we may be asked
11 to produce documentation and they were just
12 trying to get, "they," being Lilly legal, some
13 background.

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14 Q. Did you ever speak to Dr. Perahia about
15 discontinuation symptoms?

16 A. No. Not that I recall.

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17 Q. Okay. And do you recall anybody in
18 Medical or in Regulatory ever saying to you,
19 wow, I think that this label is misleading?

20 A. No.

21 Q. And obviously I don't mean that in
22 quotes. I mean, something to that effect, do
23 you ever recall having a conversation like that
24 with anybody within Eli Lilly?

25 A. I do not recall, and I think I would

1 recall if something like that were brought to my
2 attention.

3 Q. In 2012, were you ever made aware of
4 something called the QuarterWatch Report related
5 to Cymbalta?

6 A. It sounds familiar but I'm not sure. I
7 don't -- nothing specific for Cymbalta.

8 Q. Okay. I might show it to you later. I
9 just want to know do you have any independent
10 recollection of something called a QuarterWatch
11 Report that relates to Cymbalta? Do you have
12 any recollection of that?

13 A. I don't.

14 Q. Okay. Are you familiar with the
15 Institute for Safe Medication Practices?

16 A. I am.

17 Q. What is that organization?

18 A. It's a -- It's an independent business
19 that really is interested in promoting safe use
20 of -- well, safety medical practices including
21 use of medications, so they were primarily about
22 medication errors as I at least am familiar with
23 that organization but maybe more broadly in
24 terms of just safe use.

25 Q. And did you frequently read

1 publications by that organization?

2 A. No. Not -- not that I recall.

3 Q. Do you currently do that?

4 A. No.

5 Q. Okay. Is the Institution for Safe
6 Medication Practices a respected organization?

7 MR. TEEL: Objection to lack of
8 foundation.

9 THE WITNESS: My understanding is it
10 is, yes. I mean, I have certainly heard of them
11 in the -- yes.

12 BY MR. WISNER:

13 Q. Let me rephrase the question maybe.

14 Based on your experiences within Eli
15 Lilly, was the Institute for Safe Medication
16 Practices considered a reputable organization?

17 MR. TEEL: Objection. Lack of
18 foundation.

19 THE WITNESS: Yes.

20 BY MR. WISNER:

21 Q. Do you recall ever speaking to somebody
22 about the Institute for Safe Medicine Practices?

23 A. Now, we may have used ISMP for a
24 medication error project that I worked on or
25 maybe sort of wrapped up when I was working on

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1 Zyprexa with regard to mistaking the bottle of
2 Zyprexa for a bottle of Zyrtec on the pharmacy
3 shelves and the naming similarities. We worked
4 with ISMP to differentiate the labels in a way
5 that would help prevent that.

6 Q. So based on your time at Lilly, it's
7 your understanding that Lilly would actually
8 work with ISMP on occasion?

9 A. I am not a hundred percent certain ISMP
10 was that company, but I think so.

11 Q. Okay.

12 A. So my recollection is yes.

13 Q. Do you recall ever having -- Do you
14 know who Madeline Warick might be?

15 A. Yes.

16 Q. Who is she?

17 A. She is a medical -- medical -- I don't
18 know if she is a Medical Director or if she was
19 in medical.

20 Q. Did you have any occasion to interact
21 with her while she was working at Eli Lilly with
22 regards to Cymbalta?

23 A. I did.

24 Q. Okay. What was your inter -- what was
25 the nature of your working relationship with

1 her?

2 A. So she was -- I think she was in a role
3 very similar to Dr. Perahia in that she would
4 provide -- she is a physician by training, and
5 she would provide medical input, oversight into
6 clinical development activities.

7 Q. And this is a very specific question
8 but do you ever recall having a conversation
9 with her about ISMP?

10 A. I don't, no.

11 MR. WISNER: Let's take a short break.

12 MR. TEEL: Sure.

13 THE VIDEOGRAPHER: Going off the record
14 at 2:49 p.m.

15 (Whereupon, a short recess was
16 taken.)

17 THE VIDEOGRAPHER: We are back on the
18 record at 2:58 p.m.

19 BY MR. WISNER:

20 Q. Doctor -- I'm sorry, doctor. Are you a
21 doctor?

22 A. Yeah. I mean, no one -- I never refer
23 to myself as a doctor, but yes.

24 Q. But you are not a medical doctor; is
25 that right?

1 A. No.

2 Q. Okay. I might call you doctor. That's
3 just an instinctual thing but I apologize if --
4 Anyway, so let's get started.

5 Are you familiar with something that's
6 called a Core Data Sheet?

7 A. Yes.

8 Q. What is the Core Data Sheet for a
9 product?

10 A. So Core Data Sheet is a document
11 that -- an internal document that would be
12 developed to define core safety information for
13 a product; and the intent by the Core Data
14 Sheet, again, is sort of in the interest of
15 harmonization of information across labeling
16 globally.

17 Q. Would it be fair to say that labels are
18 generally derived from the information contained
19 on the Core Data Sheet?

20 A. Yes.

21 Q. And who creates the Core Data Sheet?

22 A. Well, I think it was -- At Lilly, I
23 believe that development was owned by the Safety
24 Group at Lilly, but I am not sure about this,
25 but there would have been significant need for

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1 BY MR. WISNER:

2 Q. Okay. It is true that Cymbalta is
3 approved for other indications in Europe that it
4 is not approved for in US, right?

5 A. I'm not sure actually.

6 Q. Have you ever heard of stress urinary
7 incontinence?

8 A. Oh, yes. That's right. Yes. Yes.
9 Uh-huh.

10 Q. Are you familiar with that Cymbalta is
11 indicated for that treatment of that condition
12 in different countries other than the US?

13 A. Yes. I am now that you say that, yes.

14 Q. Okay. Do you recall doing any work
15 with regards to the SUI indication in the US?

16 A. No.

17 Q. Okay. The next sentence says,
18 "Following abrupt or tapered discontinuation in
19 placebo-controlled trials, the following
20 symptoms occurred at 1 percent or greater and at
21 a significantly higher rate in
22 duloxetine-treated patients compared to those
23 discontinuing from placebo," and it lists
24 several symptoms there or side effects. Do you
25 see that?

1 A. I do.

2 Q. Okay. What is your understanding of
3 that sentence?

4 A. What the sentence is conveying that --
5 Okay. So, first of all, the systematic
6 evaluation was from placebo-controlled clinical
7 trials so that's the data source. The following
8 symptoms occurred at an incidence of 1 percent
9 or more and was higher in the Cymbalta-treated
10 patients relative to placebo patients and it
11 lists these terms.

12 Q. Now, these terms, these are MedDRA
13 terms, correct?

14 A. I think they are MedDRA terms. They
15 would be.

16 Q. Okay. So these are defined by that
17 convention that we discussed previously?

18 A. Yes.

19 Q. And it says significantly higher rate.
20 Is it your understanding that that's referenced
21 to statistical significance?

22 MR. TEEL: Objection. Lack of
23 foundation.

24 THE WITNESS: I don't know in this
25 case; but in common practice, that use of the

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1 word significantly higher would connote some
2 sort of statistical inference.

3 BY MR. WISNER:

4 Q. Well, because significantly has
5 multiple meanings, right?

6 A. Uh-huh.

7 Q. In statistics that means that the
8 numbers observed in one arm versus another arm,
9 the difference observed is not a product of
10 chance?

11 MR. TEEL: Object to the form.

12 THE WITNESS: I don't think I would
13 phrase it that way.

14 BY MR. WISNER:

15 Q. Please tell me what is your
16 understanding of statistical significance.

17 A. That there is a -- How do I phrase
18 this? That the observation is unlikely to be,
19 maybe this is what you just said, the result of
20 chance. Is that what you said?

21 Q. That's what I was saying inartfully.

22 A. That there is likely to be the result
23 of other factors basically.

24 Q. And it also significantly has a layman
25 meaning as well, right?

1 MR. TEEL: Object to the form.

2 THE WITNESS: Yes.

3 BY MR. WISNER:

4 Q. Do you know which one this is referring
5 to in this part of the label?

6 MR. TEEL: Object to the form.

7 THE WITNESS: Well, I don't know but,
8 again, typical practice would be that the
9 appearance of the word significant or
10 significantly within the USPI is referring to a
11 statistical finding.

12 BY MR. WISNER:

13 Q. And that inference is supported by the
14 fact that it's referring to placebo-controlled
15 trials related to Cymbalta?

16 A. That makes sense to me, yes.

17 Q. Okay. And then it would be an
18 essentially higher rate in the duloxetine arm of
19 those trials versus the placebo arm of those
20 trials?

21 A. That's what this is saying.

22 Q. Okay. It says the following symptoms
23 occur at 1 percent or greater. Do you
24 understand what that phrase is referring to?

25 A. Yeah. It just -- It's setting a

1 threshold essentially for the analysis that
2 based on the data that has been analyzed in this
3 case, in my view, it would appear this is a very
4 conservative approach and that you would be very
5 inclusive in the types of terms that would
6 qualify to be represented as an output of this
7 kind of analysis.

8 Q. Okay. And the -- So it would be fair
9 to infer then from this warning that there is a
10 1 percent or greater chance that upon
11 discontinuation, abrupt or tapered for Cymbalta,
12 a person would experience dizziness?

13 A. No. That's not the way this -- That's
14 not the way I would understand this. I would
15 say this is saying that for patients who
16 discontinued duloxetine relative to those who
17 discontinued placebo in trials, there was a
18 higher incidence of these events relative to the
19 placebo arm.

20 Q. Now, it doesn't say specifically what
21 the percentage for those incident rates were for
22 those specific side effects, correct?

23 A. It's only saying that they occurred at
24 least 1 percent or more of the time.

25 Q. So it's possible -- and that's

1 referring to these specific MedDRA terms, right?

2 A. Right.

3 Q. So for dizziness it's 1 percent or
4 greater?

5 A. It's saying for -- yeah, for dizziness,
6 it occurred at least at 1 percent and at a
7 higher rate than the placebo arm.

8 Q. Now, 1 percent or greater, that means
9 it's possible that dizziness occurred in a
10 hundred percent of patients, right?

11 A. It's possible. It's greater than 1
12 percent.

13 Q. And it's also possible that it occurred
14 in 1.1 percent, right?

15 A. That's right.

16 Q. So based on the information contained
17 in this label, the possible range of dizziness
18 with regards to the 1 percent is somewhere
19 between 1 and a hundred percent?

20 A. Right.

21 Q. And nowhere in that paragraph does it
22 specifically state what the percentage is for
23 each one of those MedDRA terms?

24 A. No. It's not -- This paragraph is
25 listing the, for lack of a better way of

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1 phrasing it, constellation of potential events
2 that could -- that were observed following
3 discontinuation.

4 Q. And also in that paragraph, it doesn't
5 say what the likelihood that a patient would
6 experience at least one of those symptoms,
7 correct?

8 A. No. That's not what this is conveying.

9 Q. Okay. So there is no overall incident
10 rates of just general discontinuation symptoms
11 in that paragraph?

12 MR. TEEL: Object to the form.

13 THE WITNESS: No. That's not what
14 this -- again, this is conveying here are the
15 kind of events that were observed, so for
16 healthcare professionals to understand, here are
17 the types of symptoms associated with
18 discontinuation events with Cymbalta.

19 BY MR. WISNER:

20 Q. The next paragraph reads, "During the
21 marketing of other SSRIs and SNRIs (serotonin
22 and norepinephrine reuptake inhibitors), there
23 have been spontaneous reports of adverse events
24 occurring upon discontinuation of these drugs,
25 particularly when abrupt, including the

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1 following:" And it lists again a bunch of
2 terms. Do you see that?

3 A. I do.

4 Q. Now, I want to break that down a little
5 bit here. It says during the marketing of other
6 SSRIs and SNRIs, what is that referring to?

7 MR. TEEL: Objection. Lack of
8 foundation. You can answer.

9 THE WITNESS: Yes. I'm not sure I
10 guess, but my educated guess is that this is
11 referring to sort of a class kind of labeling
12 change.

13 BY MR. WISNER:

14 Q. And it says there have been
15 "spontaneous reports of adverse events." Is the
16 phrase "spontaneous reports of adverse events,"
17 is that a term of art?

18 A. It is.

19 Q. What is that?

20 A. That's referring to postmarketing
21 Adverse Event Reports. Those are commonly
22 referred to as Spontaneous Reports.

23 Q. And can you explain to the jury what
24 spontaneous means in that context because I
25 think -- Could you please explain to the jury

1 what that means?

2 A. Yes. Spontaneous is a term that is
3 used to indicate that the terms were not
4 solicited. For example, like in a clinical
5 trial setting, the clinical trial investigators
6 ask have you had any adverse events, what were
7 those, et cetera, so you are actually soliciting
8 that information; whereas, in the postmarketing
9 setting, these would be terms, events, cases
10 that would be reported to Lilly unprompted
11 without any sort of solicitation through the
12 call center or maybe through a sales rep or
13 other mechanism.

14 Q. Okay. Is it your under -- Okay. Now
15 just take a second and just finish reading
16 through the rest of the section just so you have
17 a sense of what's in it.

18 A. Okay.

19 Q. Let me know when you are done.

20 A. Okay. I am finished.

21 Q. Keep that Exhibit 1 open to that
22 section because we are going to be referencing
23 it.

24 A. Okay.

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1 Committee, that's the Advisory Committee that we
2 were just discussing?

3 A. That is.

4 Q. Okay. And the Lilly Briefing Doc,
5 that's the document that Lilly submitted to the
6 FDA in anticipation of that meeting?

7 A. Correct.

8 Q. Can you just turn to page -- it's a
9 fairly lengthy document here.

10 A. Uh-huh.

11 Q. It runs from CYM-01939316 through
12 CYM-01939474. Is this the Briefing Document?

13 A. That's what it appears to be, yes.

14 Q. It's about 159 pages; is that right?

15 A. That's -- yep. Yes.

16 Q. And that's consistent with what you
17 remember the briefing document being that was
18 submitted to the FDA?

19 A. I actually thought it was shorter, but,
20 yes. This sounds right.

21 Q. Okay. And it says down here it says,
22 "Available for public disclosure without
23 redaction," right?

24 A. Right.

25 Q. And that was what you were mentioning

1 before, that this was actually posted and made
2 available online?

3 A. Right.

4 (Whereupon, Deposition Exhibit
5 No. 13 was marked and dated.)

6 BY MR. WISNER:

7 Q. Okay. Doctor, I have handed you what I
8 have marked as Exhibit 13, right?

9 A. Right.

10 Q. Okay. This is an E-mail exchange. If
11 you look down towards the bottom, there is an
12 E-mail from you to Bryan E. Boggs. Do you see
13 that?

14 A. I do.

15 Q. And you said, "FYI, in case you haven't
16 seen this. Includes dulox safety reviews." Do
17 you see that?

18 A. I do.

19 Q. Okay. And this is a document that's
20 Bates stamped CYM-02053002. Now, Doctor --
21 Mr. Kuntz, this -- do you know what you were
22 referring to in this E-mail?

23 A. I don't recall. I'd have to look here.
24 Okay. I actually still don't even know after
25 looking at it what this is exactly referring to.

1) Okay.

2 Q. Well, above it Bryan Boggs says,
3 "Please convene a group to discuss this posting
4 to the FDA website." Do you see that?

5 A. I do.

6 Q. And, "There are three documents I have
7 attached. I believe we have seen the first memo
8 regarding medication errors already. All of
9 these are dated 2007 and I don't believe pose
10 any issues we have not already addressed. Label
11 changes suggested within the bleeding report
12 appear to have been made already. Carole, would
13 you look at this to determine when these changes
14 were actually implemented."

15 Did I read that right?

16 A. Yes.

17 Q. Okay. So it appears that you had sent
18 a link to several documents that had been posted
19 on the FDA website; is that fair?

20 A. Uh-huh.

21 (Whereupon, Deposition Exhibit
22 No. 14 was marked and dated.)

23 BY MR. WISNER:

24 Q. Okay. I am handing you what I have
25 marked as Exhibit 14 to your deposition. This

1 is one of the attachments that Bryan had to his
2 E-mail. Do you recognize this document, Doctor?
3 Do you recognize this document?

4 A. I don't.

5 Q. What does it appear to be?

6 A. Well, it's some sort of memo from --
7 from within FDA. Medication Error Report.

8 Q. So it's a memorandum that was prepared
9 within the FDA?

10 A. Within the FDA, right.

11 Q. Okay. Do you know if this memorandum
12 was ever shared with Eli Lilly?

13 A. Well, it was -- what I think it sure
14 looks like happened is this memo was posted.
15 This was the document that was posted to FDA's
16 website and I was on a -- basically a list serve
17 or something where FDA, you know, sends out
18 updates and that's how I found this document.

19 Q. But do you know whether in 2007 this
20 document was given to Lilly?

21 A. Oh, I beg your pardon. I didn't
22 understand your -- the timing. No. I don't
23 know.

24 Q. And just to clarify, the E-mail that
25 you are mentioning that you sent, that was in

1 2009, right?

2 A. That's right.

3 Q. And this memo is dated 2007?

4 A. Right.

5 Q. Okay. Do you know whether or not in

6 2007 this memo was shared with Lilly?

7 A. I don't.

8 Q. Okay. All right. Well, this is -- and

9 in the Executive Summary it says, "During

10 routine postmarketing surveillance of medication

11 errors, DMETS identified a signal involving the

12 opening of Cymbalta capsules prior to

13 administration to achieve a lower dose of the

14 drug."

15 What is DMETS?

16 A. It's the FDA Division of Medication

17 Errors and Technical Support.

18 Q. Okay. And it says identified a signal.

19 What is your understanding of that word

20 "signal"?

21 A. Yeah. That's a -- that's a term that

22 would signify that in the review of aggregated

23 safety data from the errors database, this issue

24 came up somehow in their analysis. There is

25 lots of probably different algorithms that they

1 would have applied but --

2 Q. And you have familiarity with such
3 things as signals based on your work in the
4 Pharmacovigilance Group, right?

5 A. Yeah. That's right.

6 Q. Okay. It says here that there has been
7 a signal that opening of Cymbalta capsules prior
8 to administration to achieve a lower dose of the
9 drug.

10 Do you ever recall discussing this
11 issue at Eli Lilly in your regulatory capacity?

12 A. I don't.

13 Q. Okay. If you turn the page, on Page 2,
14 under Section 3, it says, "During routine
15 monitoring of medication errors, DMETS received
16 a case where a patient intentionally opened a
17 Cymbalta capsule to achieve a lower dose."

18 During your time at Eli Lilly, do you
19 recall ever having any discussions with anyone
20 at Eli Lilly about people opening up the
21 capsules to create smaller dosages for Cymbalta?

22 A. I don't.

23 Q. Do you recall whether or not anyone at
24 Eli Lilly took actions to update the label or
25 make changes to the US label in response to the

1 potential of patients opening up Cymbalta
2 capsules?

3 A. I don't recall that.

4 Q. Okay. If you turn to Page 3, under
5 Section C, Wrong Technique, go down midway
6 through the paragraph. It says, "One (n=1) case
7 involved opening 20 milligram capsules while
8 tapering off Cymbalta to avoid withdrawal
9 effects."

10 Do you see that?

11 A. I do.

12 Q. In this document, the FDA has
13 identified a signal and supporting that
14 identification of that signal is discussing at
15 least one incident where a patient has opened
16 the 20 milligram capsule so as to avoid
17 withdrawal effects, correct?

18 A. That's what this report is stating.

19 Q. Do you know whether or not Lilly took
20 any actions to update the label to warn patients
21 not to open up the 20 milligram capsules to
22 avoid withdrawal effects?

23 A. I don't recall.

24 Q. Do you know if Lilly, at any time,
25 considered submitting a prior approval

1 supplement to obtain smaller doses of Cymbalta
2 for the purposes of tapering?

3 A. No. I'm trying to recall if there was
4 a lower dose for the pediatric studies but I
5 just don't recall.

6 Q. Okay. So do you recall -- Well, do you
7 recall whether or not Lilly ever did try to
8 obtain a smaller than 20 milligram dose of
9 Cymbalta -- Sorry. Let me rephrase that.

10 Do you recall whether or not -- Do you
11 know whether or not Lilly ever tried to obtain
12 approval for a dosage of Cymbalta less than 20
13 milligrams?

14 A. I don't know.

15 Q. Okay. Turn to Page 6, it says, Upon --
16 under Section 3, the paragraph under
17 Section 3 -- Well, the section reads Institute
18 of Safe Medicine Practices Outpatient Medication
19 Errors. And then underneath that it says, "Upon
20 DMETS request, the Institute for Safe Medication
21 Practices (ISMP) searched their database for
22 outpatient medication errors involving
23 Cymbalta."

24 Do you -- The ISMP, that's the
25 organization that published that QuarterWatch

1 report we mentioned earlier, right?

2 A. Right.

3 Q. And it appears here that the FDA's
4 DMETS has requested data from that organization?

5 A. Yes. That's what it looks like.

6 Q. Okay. If you turn to Page 7 under
7 Section A, Patients Attempting to Reduce or
8 Avoid Adverse Effects of Cymbalta, do you see
9 that section?

10 A. Yes.

11 Q. All right. Second to the last sentence
12 in that paragraph, the first paragraph it reads,
13 "Three cases (n=3) reported patients opening the
14 capsules to create a dose of Cymbalta less than
15 20 milligrams in an attempt to reduce the
16 adverse events associated with the
17 discontinuation of Cymbalta."

18 Would it have been possible for Lilly
19 to have submitted an SNDA -- or sorry -- a
20 preapproved -- Would it have been possible for
21 Lilly to have submitted a Prior Approval
22 Supplement to obtain smaller doses --
23 approval -- to obtain approval of smaller doses
24 of Cymbalta below 20 milligrams?

25 MR. TEEL: Objection. Calls for

1 speculation. Lack of foundation.

2 THE WITNESS: I mean, it's not as

3 simple as just submitting that, you know,

4 request to FDA. They would expect to have data

5 to support the use of that and you would have to

6 do quite a bit, I would think, of clinical

7 evaluation of that lower dosage form.

8 BY MR. WISNER:

9 Q. Do you know if Lilly ever did conduct
10 clinical trials to evaluate the discontinuation
11 effects of a subtherapeutic dose below 20
12 milligrams?

13 A. I'm not aware.

14 Q. Okay. Based on your understanding of
15 the CBE regulation, would Lilly have been able
16 to make changes to the Cymbalta label advising
17 patients that there was no way to taper below 20
18 milligrams?

19 MR. TEEL: Objection. Again, lack of
20 foundation.

21 THE WITNESS: I'm not sure I quite
22 understand what you are asking. Can you
23 rephrase it?

24 BY MR. WISNER:

25 Q. Using the CBE regulation, would Lilly

1 have been able to make changes to the
2 discontinuation warning in the Cymbalta label
3 for the US advising patients that there was no
4 way to taper below 20 milligrams?

5 A. Well, again, I think it could have been
6 possible is the best way to answer that
7 question.

8 Q. Thank you. You can't say for sure
9 right now that it would have been impossible?

10 A. Yeah. That's right.

11 Q. Okay. Do you recall ever being
12 consulted about potential changes to the
13 Japanese label for Cymbalta?

14 A. I believe this was something we may
15 have discussed in preparation for today. I am
16 not a hundred percent sure.

17 Q. Okay. Well, independent of what any
18 lawyer may have said to you --

19 A. Right.

20 Q. -- do you recall that your approach to
21 make changes -- your approach about the Japanese
22 label?

23 A. I honestly, at the moment, I don't
24 remember that. For some reason, though, there
25 is something in that -- anyways, I'm sorry. I

* * *

C E R T I F I C A T E

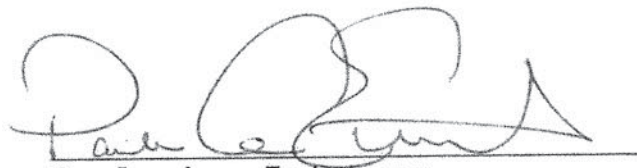
I, Paula Ann Erickson, Certified Professional Reporter, Registered Professional Reporter and Notary Public, do hereby certify:

That the witness in the foregoing deposition named was present at the time and place therein specified;

That the said proceeding was taken before me as a Notary Public at the same time and place and was taken down in shorthand writing by me;

That this transcript is a true and accurate transcript of my shorthand notes so taken, to the best of my ability.

I further certify that I am neither counsel for nor related to or employed by any of the parties to this action and that I am not a relative or employee of any counsel employed by the parties hereto or financially interested in the action.



Paula Ann Erickson
Certified Shorthand Reporter
Registered Professional Reporter
License No. 084-003899
Notary Public

Dated this 15th day
of May, 2015.

Ali v. Eli Lilly and Company
Hagan-Brown v. Eli Lilly and Company
Lilly's Objections to Plaintiffs' Deposition Designations
Matthew Kuntz

Lines	Objection(s)	Explanation
30:25-31:5	402	Mr. Kuntz's lack of recollection as to whether Lilly submitted a Changes Being Effected (CBE) label change is irrelevant. Moreover, Lilly's CBEs related to products other than Cymbalta are irrelevant.
31:6-31:14	402	Mr. Kuntz's recollection that Lilly submitted Prior Approval Supplements to FDA and that he "wouldn't be surprised" if CBEs were submitted to FDA is irrelevant. The question is not tied to Cymbalta in any way.
31:15-31:25	402 Lack of foundation.	Mr. Kuntz's testimony that CBEs and Prior Approval Supplements were normal in Lilly's course of business is irrelevant. Counsel's question whether such submissions are common in Lilly's interactions with FDA lacks foundation to establish that Mr. Kuntz can speak to the course of Lilly's interactions with FDA.
56:4-11	403 Lack of foundation.	Testimony about Mr. Kuntz's recollection whether Lilly had any "regulatory activities" concerning discontinuation is unduly prejudicial. Plaintiffs are improperly and falsely suggesting that discontinuation symptoms were not important to Lilly and that Lilly did not take any actions related to discontinuation symptoms. Additionally, counsel's question about whether Mr. Kuntz recalls regulatory interactions related to discontinuation symptoms lacks foundation to establish that Mr. Kuntz can testify to the breadth of Lilly's interactions with FDA concerning Cymbalta.
65:5-65:15	402 403	Mr. Kuntz's on-the-spot recollection of discontinuation symptoms is irrelevant and prejudicial where discontinuation symptoms are listed in great detail in Cymbalta's label, clinical trials, and various other scientific and regulatory documents. Counsel's "memory test" is designed to mislead the jury to believe that Lilly did not adequately research or understand the symptoms.
65:16-66:1	402	This designation will be subject to Lilly's

Lines	Objection(s)	Explanation
	403 MIL	European Labeling MIL. Additionally, Mr. Kuntz's on-the-spot recollection of the frequency of discontinuation symptoms is irrelevant and prejudicial where their frequency is listed in great detail in Cymbalta's label, clinical trials, and various other scientific and regulatory documents.
66:2-66:8	402 403	Mr. Kuntz's testimony concerning whether he considered discontinuation symptoms "important" is irrelevant and prejudicial. Lilly's and its employees' views about the relative importance of specific side effects is irrelevant, and risks undue prejudice in suggesting that Lilly prioritized certain side effects or safety issues over others.
66:13-66:17	402 403	Mr. Kuntz's lack of recollection of any discussion within Lilly about possible deficiencies in the Cymbalta label concerning discontinuation is irrelevant and prejudicial. Plaintiffs are attempting to suggest that internal Lilly discussions about the label were not important enough to the company to be remembered.
66:18-67:3	402 403	Mr. Kuntz's recollection that the only conversation he could recall concerning discontinuation symptoms was related to litigation is irrelevant and prejudicial. Mr. Kuntz's recollection about litigation was undoubtedly jogged by his involvement in this litigation and the recency of such communications, whereas his natural lack of recollection about older communications should not be allowed to prejudice Lilly by suggesting that Lilly's only concern was with legal liability rather than patient safety.
67:4-67:13	402 403	Mr. Kuntz's recollection that the only conversation he could recall concerning discontinuation symptoms was related to litigation is irrelevant and prejudicial. Mr. Kuntz's recollection about litigation was undoubtedly jogged by his involvement in this litigation and the recency of such communications, whereas his natural lack of recollection about older communications should not be allowed to prejudice Lilly by suggesting that Lilly's only concern was with legal liability rather than patient safety.

Lines	Objection(s)	Explanation
67:14-67:16	402 403	Mr. Kuntz's lack of recollection of any discussion with Dr. Perahia about discontinuation symptoms is irrelevant and prejudicial. Plaintiffs are attempting to suggest that internal Lilly discussions about the label were not important enough to the company to be remembered.
67:17-68:2	402 403	Mr. Kuntz's lack of recollection of any discussion within Lilly about possible deficiencies in the Cymbalta label is irrelevant and prejudicial. Plaintiffs are attempting to suggest that internal Lilly discussions about the label were not important enough to the company to be remembered.
68:14-24	MIL 402 403	This designation will be subject to Lilly's MIL about the QuarterWatch publication. Moreover, Mr. Kuntz's independent knowledge of and familiarity with the organization that publishes QuarterWatch is irrelevant as well as unduly prejudicial in that Mr. Kuntz's familiarity is based on the organization's work related to confusion about drug names (<i>see</i> Kuntz Dep. at 69:23-70:5) rather than their publications about labeling adequacy.
69:14-19	MIL Lack of foundation.	This designation will be subject to Lilly's MIL about the QuarterWatch publication. Moreover, counsel's question lacks foundation as to Mr. Kuntz's understanding about other Lilly employees' views about the Institute for Safe Medication Practices.
70:6-71:9	MIL 402	This designation will be subject to Lilly's MIL about the QuarterWatch publication. Moreover, Mr. Kuntz's lack of recollection as to whether Institute for Safe Medication Practices was the organization he recalled or whether he ever discussed it with Dr. Wohlreich is irrelevant
93:19-94:2	402 403 Lack of foundation.	Counsel's question about whether the Cymbalta label refers to the concept of statistical significance lacks the necessary foundation of Mr. Kuntz's knowledge of statistical significance. Moreover, Mr. Kuntz's understanding of whether the label refers to statistical significance is irrelevant and prejudicial in suggesting that the language in the label connotes only a statistical

Lines	Objection(s)	Explanation
		meaning.
94:7-94:13	402 403 Lack of foundation.	Counsel's question about the concept of statistical significance lacks the necessary foundation of Mr. Kuntz's knowledge of statistical significance. Moreover, Mr. Kuntz's understanding of whether the label refers to statistical significance is irrelevant and prejudicial in suggesting that the language in the label connotes only a statistical meaning.
97:8-97:20	402 403 Lack of foundation.	Lilly has not generally objected to questions asking Mr. Kuntz for his understanding of the contents of Cymbalta's label to the extent that they reflect the underlying text of the label and/or the underlying data. However, questions about whether the "1% or greater" language could include effects that occurred at a rate of 100% lack foundation. No discontinuation symptom in any study occurred at a rate even approaching 100%. (The most common single symptom in the 2005 Perahia study occurred at a rate of 12.4%.) Plaintiffs' designation therefore falsely suggests that some symptoms may have occurred at a rate approaching 100% and is therefore irrelevant, prejudicial, misleading, and likely to cause confusion.
99:4-99:12	Lack of foundation.	Counsel's question about the "marketing of other SSRIs and SNRIs" lacks foundation to establish that Mr. Kuntz has an understanding of the marketing of other SSRIs and SNRIs.
196:7-202:5	402 403	Mr. Kuntz's testimony that he does not recall an email exchange regarding patients breaking open capsules is irrelevant, and risks prejudice to Lilly by implying that Lilly did not take FDA reports about patient issues seriously enough to allow Lilly employees to later recall them. In addition, evidence regarding the opening of capsules is irrelevant and prejudicial in this case where neither Plaintiff alleges that she broke open capsules and neither prescriber instructed Plaintiff to break open capsules. Moreover, Plaintiffs voluntarily withdrew their design defect claims.
202:10-202:14	402 403	Evidence regarding doses below 20mg are irrelevant and prejudicial in this case where neither Plaintiff took 20mg at any point and where neither prescriber testified that he or she

Lines	Objection(s)	Explanation
		sought a dosage below 20mg. Moreover, Plaintiffs voluntarily withdrew their design defect claims.
202:15-204:7	402 403 MIL	This designation will be subject to Lilly's MIL about QuarterWatch. In addition, evidence regarding an FDA document regarding the opening of capsules is irrelevant and prejudicial in this case where neither Plaintiff alleges that she broke open capsules and neither prescriber instructed Plaintiff to break open capsules. Moreover, Plaintiffs voluntarily withdrew their design defect claims.